IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION	)	MDL Docket No. 08-md-1941-GMS

DEFENDANTS' RESPONSE TO PLAINTIFFS' CLAIM CONSTRUCTION BRIEF

OF COUNSEL:

Steven E. Feldman
Sherry L. Rollo
HUSCH BLACKWELL SANDERS LLP
120 S. Riverside Plaza, 22nd Floor
Chicago, IL 60606
Tel: (312) 655-1500

Dated: April 24, 2009
913401 / 32533 / 32339 (Alfi)

Richard L. Horwitz (#2246)
David E. Moore (#3983)
D. Fon Muttamara-Walker (#4646)
POTTER ANDERSON & CORROON LLP
Hercules Plaza 6th Floor
1313 N. Market Street
P.O. Box 951
Wilmington, DE 19899
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com
fmuttamara-walker@potteranderson.com

Attorneys for Defendants Apotex Inc. , Apotex Corp. and Mylan Pharmaceuticals Inc

Also Filed on Behalf of Defendants Torrent Pharma Inc., Torrent Pharmaceuticals Ltd., Actavis South Atlantic LLC, Par Pharmaceutical, Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited, Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Ltd., Wockhardt Limited, and Wockhardt USA, Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

I. INTRODUCTION

Claims are to be interpreted as written, not as the patentee wishes they had been written. *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) ("Thus, in accord with our settled practice we construe the claim as written, not as the patentees wish they had written it"). Further, extrinsic evidence in the form of expert declarations cannot be used to change the meaning of the claims under the guise of interpretation. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) ("[E]xtrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence. The effect of that bias can be exacerbated if the expert is not one of skill in the relevant art or if the expert's opinion is offered in a form that is not subject to cross-examination"); *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998); *Phillips Petroleum Co. v. Huntsman Polymers Corp.*, 157 F.3d 866, 870 (Fed. Cir. 1998) ("When the intrinsic evidence unambiguously delineates the scope of the patent, resort to extrinsic evidence, including expert testimony, is unnecessary."); *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed. Cir. 1997); *Cf. Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1585 (Fed. Cir. 1996) (stating that "dictionaries...are accessible to the public in advance of litigation [and are therefore] to be preferred over opinion testimony, whether by an attorney or artisans in the field of technology to which the patent is directed.").

Sanofi's proposed claim constructions violate both of the above canons of claim construction and should be rejected. Repeatedly, Sanofi attempts to use claim construction as a mechanism for redrafting the claim language and to revise its claims in hopes of curing defects in them. In an effort to bolster its proposed revisions to the claim language, Sanofi improperly submits the opinion testimony of two retained experts as support for Sanofi's proposed claim

constructions, including the opinions of Dr. O'Leary who has received funding from Sanofi dating back to 1995. *See* Exhibit A to the Declaration of Dr. Michael P. O'Leary in Support of Sanofi-Aventis and Sanofi-Aventis U.S. LLC's Opening Claim Construction Brief at ("O'Leary Decl.") at pp. 11-12.

II. DEFENDANTS' RESPONSE TO PLAINTIFFS' PROPOSED CONSTRUCTIONS OF CLAIM TERMS

A. THE '491 PATENT

1. "Benign Hypertrophy of the Prostate of Alpha-Adrenergic Origin."

Perhaps the most glaring example of Sanofi's revisionist approach to claim construction is its proposed interpretation of Claim 5 of the '491 patent. That claim recites a method for treating dysuria "in male patients having benign hypertrophy of the prostrate [sic prostate] of alpha-adrenergic origin." Sanofi, improperly relying on the opinion testimony of Dr. O'Leary, argues that this language should be rewritten as "benign enlargement of the prostate treatable by an alpha-adrenergic antagonist." (*Plaintiffs' Opening Claim Construction Brief* ("Pl.s' Br.") at 11-12.) There are several problems with this proposed revision to the claim. First and foremost, this is not what the claim says. The claim refers to "treating dysuria in male patients having benign hypertrophy of the prostate . . ." Dysuria is a medical condition. The claim says nothing about treating the prostate which is a gland.

At page 12 of its brief, Sanofi incorrectly asserts that there is support in the '491 patent specification for treating benign enlargement of the prostate "by relaxing the smooth muscle of the bladder neck and prostate." *Id.* (citing '491 patent, JA2 at cols. 2:5-3:20). But that section of the specification does not mention relaxing the smooth muscles of the prostate at all. Starting at col. 2, line 5, the specification talks about tests done on tissue from male rabbit bladders and urethras, not prostates. The only mention of prostate occurs at col. 2, line 20, in reference to a

"5mm ring of urethra" that was taken from the region "situated between the base of the bladder and the prostate." ('491 Patent, JA2 at col. 2:19-21.) Thus, the prostate is being used merely as a point of reference. The tissue at issue is from the urethra, not the prostate. Contrary to Sanofi's suggestion, this testing has nothing to do with a hypertrophic prostate.

Furthermore, the claim requires that the "benign hypertrophy of the prostate" be of "alpha adrenergic origin." There is absolutely no support in the specification for hypertrophy of the **prostate** being of alpha adrenergic origin. The specification does refer to the treatment of dysuria that is of alpha adrenergic origin, but it says nothing about hypertrophy of the prostate being of alpha adrenergic origin.

> Patients who may be treated are, for example, men and women who have bladder neck disease, or men who have benign hypertrophy of the prostrate [sic] **with dysuria of alpha-adrenergic origin**.

'491 Patent, JA2 at col. 1:40-44 (emphasis added).

In that case the passage from the specification "of alpha-adrenergic origin" modifies "dysuria," the condition the treatment for which alfuzosin is supposedly described. But, although Sanofi could have chosen to replicate the language of the specification in the claim to describe its supposed invention, it chose not to do so. Instead, in the claim, the phrase "of alpha-adrenergic origin" modifies "benign hypertrophy of the prostrate" [sic prostate]. Rules of claim construction require that such difference be invested with meaning and be respected. This court should reject Sanofi's invitation to ignore that difference. Here, the patentee drafted the claim so that the "benign hypertrophy of the prostate" is "of alpha-adrenergic origin." This requires that the benign hypertrophy be "caused by hyperactivity of the alpha adrenergic receptors." (*Defendants' Opening Claim Construction Brief* ("Def.'s Br.") at 5.)

Plaintiffs also argue that Defendants' interpretation of what the claim actually says is incorrect because it "lacks scientific basis, as there is no evidence in medical or scientific literature that BPH is 'caused by hyperactivity of α-adrenergic receptors.'" (Pl.'s Br. at 15.) But Defendants are simply construing the claim language as Sanofi chose to write it. If the claim language "lacks scientific basis," Plaintiffs cannot use claim construction as a mechanism to correct it. The Federal Circuit has repeatedly and consistently declined to redraft claim language. *Chef America,* 358 F.3d at 1374 ("Even a nonsensical result does not require the court to redraft the claims of the patent."); *See, e.g., Allen Eng'g Corp. v. Bartell Indus., Inc.,* 299 F.3d 1336, 1349 (Fed. Cir. 2002) ("It is not [the Court's] function to rewrite claims to preserve their validity."); *Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.,* 214 F.3d 1302, 1308-09 (Fed. Cir. 2000) ("Moreover, having concluded that the amended claim is susceptible of only one reasonable construction, we cannot construe the claim differently from its plain meaning in order to preserve its validity (upon which we do not opine").); *Process Control Corp. v. Hydreclaim Corp.,* 190 F.3d 1350, 1357 (Fed. Cir. 1999) ("Where, as here, the claim is susceptible to only one reasonable construction . . . we must construe the claims based on the patentee's version of the claim as he himself drafted it."). Sanofi's revisionist approach was expressly rejected in *Chef America* where the Federal Circuit held that "[the Court] must construe the claims based on the patentee's version of the claim as he himself drafted it." *Chef America, Inc.,* 358 F.3d at 1374. The claim in *Chef America* required "heating the resulting batter-coated dough to a temperature in the range of about 400 degrees F to 850 degrees F." *Id.* at 1373. However, if the claimed process was followed as written and the batter-coated dough was heated to a temperature in the range of 400 to 850 degrees F, the dough would burn. *Id.* The resultant product would not be "dough products suitable for freezing and finish cooking to a light, flaky, crispy texture," as

recited in the patent, but rather, would resemble a "charcoal briquet." *Id.* at 1373. To insure that the patented process accomplished the patent's stated objective Chef America urged the court to construe that the 400°F - 850°F temperature requirement was directed to the oven wherein the heating occurred, rather than to the temperature of the dough. *Id.* at 1373-74. The court declined to redraft the claim language to make the claim operable or to preserve the claim's validity. *Id.* at 1374 (refusing to interpret and rewrite the use of unambiguous word "to" in the claim to mean "at").

Sanofi also argues that Defendants' construction is improper because it defines each word individually. (Pl.'s Br. at 14-15.) There is nothing wrong with defining the actual claim language as written. For example, Sanofi complains that Defendants define the word "origin" in the phrase "of alpha-adrenergic origin" to mean "caused by." But Sanofi does not offer an alternative definition. Nor does Sanofi offer a proposed definition that takes into account the claim language as written. If origin does not mean "caused by," then what does it mean?

Sanofi also incorrectly argue that the term "hypertrophy" is interchangeable with "hyperplasia." (Pl.'s Br. at 13.) Again, these are distinct words that Sanofi chose, with distinct meanings. Hypertrophy refers to the enlargement of the prostate through an increase in size of the cells and hyperplasia refers to the enlargement of the prostate through an increase in the number of cells. *See, e.g.*, **Exhibit E** of Def.'s Br. at 800-01; **Exhibit F** of Def.'s Br. at 677-78. A person of ordinary skill in the art would have understood the significant difference between the two terms. These terms had these distinct definitions during the relevant time frame and the patentee specifically chose the term hypertrophy. It is not the Court's obligation to rewrite the claim to include hyperplasia now. The fact that Sanofi cites to certain references that equate the two terms for purposes of that reference only does not indicate that a person of ordinary skill in

the art would understand these terms are interchangeable. *See e.g.* Exhibit 12 to Pl.'s Br. ("Note that the terms hyperplasia and hypertrophy are used interchangeably ***for this chapter*** to describe the enlarged prostate" (emphasis added)). Rather, it shows that a person of ordinary skill in the art would expect notification that the terms were being used interchangeably, if in fact this is what the patentees were intending, as is seen in the reference on which Sanofi relies. The '491 patent makes no such special definition equating hypertrophy and hyperplasia. As such, hypertrophy should be defined as distinct from hyperplasia. *In re Paulsen,* 30 F.3d 1475, 1481 (Fed. Cir. 1994) (quoting *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387-88 (Fed. Cir. 1992) ("'Where an inventor chooses to be his own lexicographer and to give terms uncommon meanings, he must set out his uncommon definition in some manner within the patent disclosure' in a way to give one of ordinary skill in the art notice of the change")).

2. "Bladder Neck Disease" and "Neurological Disorder."

This case has nothing to do with the use of alfuzosin to treat bladder neck disease or neurological disorders. Neither Sanofi's label nor Defendants' proposed labels indicate a use for treatment of these conditions. The labels are limited to the treatment of signs and symptoms of BPH. Indeed Sanofi's own expert agrees that bladder neck disease and neurological disorders are not the same as BPH. "[T]he specification and claims of the '491 patent provide that alfuzosin can be used to treat dysuria resulting from disorders other than BPH, such as bladder neck disease and neurological disorders, which do not necessarily involve an enlarged prostate." (O'Leary Decl. at ¶ 31. (emphasis added)) Here there is no infringement for treatment of dysuria caused by bladder neck disease and neurological disorders. It is nonsensical to waste the Court's time disputing terms in claims that cannot in good faith be asserted against the Defendants. However, Sanofi has refused to clarify whether this claim is being asserted against Defendants and therefore it is necessary to construe the meanings of these terms.

Defendants' constructions for "bladder neck disease" and "neurological disorder" are specifically supported by the intrinsic evidence. The patent specification identifies both conditions as separate and distinct from afflictions occurring in people who suffer from disturbances in micturition. Sanofi suggest that these terms should take their plain and ordinary meaning. Again, however, Sanofi fails to provide what that meaning is. (Pl.'s Br. at 10-11.)

The phrase "bladder neck disease" should be construed as "a disease of the vesico-urethral segment, distinct from benign hypertrophy of the prostate." The patent specifically defines the bladder neck, stating alpha-adrenergic receptors are localized "in the posterior of urethra and the vesico-urethral segment, or neck". ('491 Patent, JA2 at col. 2:67-68.) Sanofi incorrectly asserts that Defendants' definition somehow prohibits a patient from having bladder neck disease and benign hypertrophy of the prostate. (Pl.'s Br. at 11.) To the contrary, Defendants' definition correctly defines bladder neck disease as a separate condition from benign hypertrophy of the prostate.

The phrase "neurological disorder" is correctly defined as "disorders of the nervous system, such as paraplegia and multiple sclerosis." The specification of the '491 patent defines neurological disorder by stating "[o]ther patients who may be treated include those with neurological disorders such as paraplegia or multiple sclerosis". ('491 patent, JA2 at col. 1:45-47.) Sanofi incorrectly suggests that Defendants' definition is limiting the scope of neurological disorders to only paraplegia and multiple sclerosis as Sanofi suggests. (Pl.'s Br. at 11.) Rather, Defendants have merely set forth the same definition the applicant provided in the specification.

3. "Effective Dysuria Controlling, Non-Toxic Amount of Alfuzosine."

Defendants correctly request the Court to construe the full claim phrase "effective dysuria controlling, non-toxic amount of alfuzosine" of claim 1 to mean "a 0.5 – 10 mg amount of alfuzosine or such other amount that reduces the incidence or severity of dysuria." (Def.'s Br. at

3.) We know from Claim 3[1], which depends from Claim 1 - and thus is encompassed by that broader independent claim - that this effective dysuria controlling, non-toxic amount of alfuzosine, must at least encompass 0.5-10 mg, because claim 3 requires "administering from 0.5 to 10 mg of alfuzosine." This is the sole dosage range of alfuzosin for adult humans disclosed and taught by the specification. No other "effective dysuria controlling, non-toxic amount" is provided. How much less or additional amounts would be an "effective, dysuria controlling, non-toxic amount" is not clear from the specification. But these are defects in the patent, not a problem with the claim construction.

Seeking to avoid the issue entirely, Sanofi argues that this phrase does not need construction and instead should be given its "ordinary" meaning. (Pl.'s Br. at 9.) However, Sanofi neglects to articulate what the "ordinary" meaning of this phrase is or what a person of ordinary skill in the art would have understood this phrase to mean. Indeed, since Sanofi's patent supposedly discloses the novel invention of using alfuzosine in an effective amount to control dysuria, Sanofi fails to explain how one skilled in the art would have understood this phrase without reference to the specific amounts and range taught in the patent.

Sanofi asks the Court to define "dysuria controlling" as "dysuria treating" but that is doubly unhelpful because it (1) tells us nothing about the meaning of the rest of the phrase (*i.e.*, the words "effective...non-toxic amount") and (2) substitutes the word "treating" for "controlling" with no explanation why this improves the understanding of the meaning of the claim. In sum, Sanofi's proposal for dealing with this phrase is nothing more than an abdication of the duty to construe it. On the other hand, Defendants' proposed construction gives a specific

[1] Claim 3: "A method according to claim 1 comprising administering from 0.5 to 10 mg of alfuzosine or the corresponding amount of a pharmaceutically acceptable salt thereof."

amount for construing the phrase "effect...non-toxic amount" (*i.e.* "a 0.5 – 10 mg amount of alfuzosine") which also improves the understanding of the meaning of the claim as a whole.

4. "Dysuria."

The parties agree that the definition for the term dysuria includes "painful urination." The definition follows directly from several authoritative medical texts, including the Merck Manual, cited in Defendants' opening submission. Another leading dictionary at the time, Mosby's Medical Dictionary (1983) confirms "painful" as the generally accepted definition of dysuria at the time. *See* Mosby's Medical & Nursing Dictionary (1983) attached hereto as **EXHIBIT K** (defining dysuria as "painful urination, usually the result of a bacterial infection or obstructive condition in the urinary tract. The patient complains of a burning sensation when passing urine, and laboratory examination may reveal the presence of blood, bacteria, or white blood cells. Dysuria is a symptom of such conditions as cystitis, urethritis, prostatitis, urinary tract tumors, and some gynecological disorders.").

Having conceded, as it must, that the definition of dysuria encompasses painful urination, the only remaining question is whether that definition also should include "difficult" urination as an element. As demonstrated by the Merck Manual and Mosby's, "difficult urination" is not typically part of the definition of dysuria. Indeed, the term "difficult urination" appears nowhere in the '491 patent specification. Furthermore, the addition of the word "difficult" adds needless complication to the definition of dysuria because the term difficult is itself undefined and subject to several disparate meanings.

Sanofi, argues that the term dysuria can include "difficult urination" because the patent gives an example of using alfuzosin to render urination "easier to initiate." (Pl.'s Br. at 8.) Sanofi also argues by inference that if alfuzosin makes urination "easier to initiate," those patients taking it must have had "*difficulty* with micturition, or urination," prior to taking

alfuzosin. (*Id.* at 6.) Sanofi also cites to the portion of the '491 patent specification that indicates that alfuzosin can be used to treat patients "suffering from neurological disorders such as paraplegia or multiple sclerosis, for whom the ***disturbance*** of micturition also responds to alfuzosine." ('491 patent, JA1, at col. 1:44-48 (emphasis added).) However, the quoted portions of the specification are referring to the effect that alfuzosin can have on the body, and certainly do not define the condition of dysuria. As the patent explains, alfuzosin will relax the smooth muscle originating from the base of the bladder and the urethra and consequently help *initiate* urination. This is so regardless of whether the patient was having difficulty urinating in the first place.

The portions of the patent specification and expert testimony on which Plaintiff relies to support inclusion of the word difficult in the definition of dysuria refer only to difficulty initiating urination. (*See* '491 Patent, JA3 at col. 3:18-19 ("In most cases, the treatment per os [by mouth] enabled micturition [urination] to be rendered easier to initiate.").) Sanofi's brief is also limited to arguments regarding difficulty initiating. (Defs.' Br. at 6.) Sanofi argues explicitly that the '491 patent refers to methods to make "urination easier". (Pl.'s Br. at 6-7.) There is no mention in the patent specification or even in Sanofi's Brief that dysuria would encompass any other difficulty. Even the extrinsic evidence offered by Sanofi offers that the term "difficult" should be limited to difficulty initiating. The declaration of Dr. O'Leary submitted by Plaintiffs states "[o]ne of ordinary skill would have understood this statement to mean that the claimed invention would make it easier for patients to initiate". ("O'Leary Decl. at ¶ 28.) Therefore, to the extent that difficult is imported into the definition of dysuria, it should be limited to difficulty initiating urination.

B. THE '940 PATENT

1. "Layer."

Sanofi's overbroad definition of "layer" ignores the clear and consistent disclosure in the patent of only three specific layers, each of which has a distinct composition and separate functions. The term "layer" is nowhere described in **any** context other than in reference to the three claimed tablet layers and is rendered meaningless at the broad level proposed by Sanofi. Under Sanofi's proposed definition of "layer" ("distinct tablet portion with specific functional properties and composition"), *any* tablet portion that performs *any* function would be a "layer." (Pl.'s Br. at 17.) The term "layer" is used throughout the '940 patent in accordance with its common meaning, as "one thickness, course, or fold laid or lying over or under another" as illustrated in Figures 1-2 and every example. There is simply no support in the '940 patent for a construction that replaces "layer" with "portion" and ignores the clear structural limitation imposed by the claimed first, second, and third layers.

Defendants maintain that each of the three recited layers must be a separate and distinct physical layer from each other layer that is present. The plurality of discrete layers having distinct compositions and different functions is expressly recited in Claim 1 cannot be erased from the claim as Sanofi proposes. *See, e.g.*, *AFG Indus., Inc. v. Cardinal IG Co.*, 375 F.3d 1367, 1373 (Fed. Cir. 2004) (claim reciting a 5-layered coating structure including separate zinc oxide layers not infringed by a unitary structure produced by successive applications of zinc oxide). Just as in *AFG*, where the court considered both the structure and properties of a deposited coating to determine whether it constituted a "layer" within the meaning of the claim at issue, it is proper for Defendants to insist that the separate layers recited in Claim 1 be defined both by distinct structures and functions. *Id.*

Tellingly, all of the intrinsic evidence cited by Sanofi in support of its proposed construction of "layer" only refers to the claimed first, second, and third layers. (D.I. 62, Exh. C, p. 8-9). On this record, Sanofi's proposed construction of "layer" that may include tablet portions or ingredients other than layers 1-3 as described is not useful and does not inform the meaning of the term "layer" as used in the claims.

2. "Coating."

Sanofi proposes to define coating as a "***covering*** . . . that [] may be used to ***offer protection*** or slow the start of drug release." (Pl.'s Br. at 16). Inconsistently, it argues that "neither the claims nor the specification limits the coating to the exterior of the tablet." *Id.* Sanofi's proposed construction makes no sense. A tablet "covering" cannot reside within the tablet interior, and cannot ***offer protection*** or ***slow the start of drug release*** unless it is on the exterior of the tablet, as Defendants have proposed.

Moreover, Sanofi's argument that the claimed coating can be insoluble (as well as well as soluble) is unsupported by the specification. Sanofi and their declarant Dr. McGinity rely on a single statement from the patent that the coating may be "soluble . . . or alternatively permeable" to mean that the coating may be soluble or insoluble. "Alternatively permeable" does not mean insoluble and Sanofi cites no support for its extrapolation. If the coating were insoluble, it could not dissolve in the stomach or intestinal tract or otherwise be digested. Nothing in the intrinsic evidence supports such a construction.

3. "Auxiliary Substance."

Sanofi and Defendants agree that the "auxiliary substance" of Claim 1 gives the preparation of the claims suitable properties of compressibility and allows the release of alfuzosin hydrochloride within a predetermined time period. (D.I. 62, Ex. C, p. 2). The parties

disagree only on whether the term "auxiliary substance" may encompass a claimed "hydrophilic polymer." Under well-recognized principles of claim construction, it cannot.

First, the language of Claim 1 recites the second layer as "formulated with a hydrophilic polymer *and* with an auxiliary substance." By reciting a hydrophilic polymer separately from an auxiliary substance, the claim language itself mandates that these be different ingredients in the layer, and that the auxiliary substance does not include within its scope any hydrophilic polymer that is separately required by the claim. Sanofi's interpretation, under which a hydrophilic polymer could also be an auxiliary substance, would erase one of these limitations from the claim. Under Sanofi's proposed construction, a composition consisting only of an active ingredient and a hydrophilic polymer could infringe all of the claims, because the hydrophilic polymer could also be an "auxiliary substance," as well as a "hydrophilic excipient" and a "hydrophilic diluent." For this reason, Defendants' construction requires that the "hydrophilic polymer" recited in Claim 1 be a different substance than the "auxiliary substance" in the second layer, and a different substance than the "hydrophilic diluent" and the "hydrophilic excipient."

The very use of the term "auxiliary" clearly states that a different substance from the hydrophilic polymer is required, because the hydrophilic polymer cannot be "auxiliary" to itself. The term "auxiliary" in Claim 1 refers to a separate substance, and in accordance with the universally accepted meaning of this common term, the "auxiliary substance" "functions or serves in a supplementary often subordinate position" (WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, *s.v.* "auxiliary" attached hereto as **EXHIBIT L**) and "function[s] in a subsidiary capacity." (*Id.*).

Second, the intrinsic evidence wholly supports a construction of "auxiliary substance" that does not include "hydrophilic polymer." The '940 patent specification describes them as

separate elements contained within the second layer ("this layer being formulated with hydrophilic polymers *and* with other auxiliary substances") ('940 patent, JA000094 at col. 2:4-15), and the prosecution history accords with this definition. In particular, applicants stated to the Patent Office during prosecution that examples of auxiliary substances were described in the specification at ('940 patent, JA000095 at col. 3:30-67), as well as Examples 1A and 2A. *See* JA000307. Nowhere are hydrophilic polymers described as auxiliary substances.

Sanofi's conclusory argument that nothing in the claims, specification and prosecution history would teach that an auxiliary substance cannot be a hydrophilic polymer is unsupported by any fact, and squarely contradicted by a plain reading of the intrinsic record.

4. "Hydrophilic Polymer."

Plaintiffs and defendants agree that the claim term hydrophilic polymer is defined with reference to the list of polymers set forth in the patent ('940 patent, JA000094-95 at col. 2:65-3:10). Defendants disagree that the list is dispositive of the claim construction issue, because the scope the term "hydrophilic polymer" was clearly narrowed during patent prosecution. As set forth in Defendants' opening brief, the list of hydrophilic polymers in the patent was originally claimed in the '940 patent application. The PTO rejected Claim 8, and the applicants acquiesced in the rejection by amending Claim 8 and narrowing its scope. (*See* Def.'s Br. at 15-17.)

Sanofi has not challenged the fact that Claim 8 was narrowed during prosecution, and has not provided any reason why the effect of that amendment is a concomitant narrowing of the scope of the term "hydrophilic polymer" in all of the '940 patent claims. Tellingly, Sanofi fails even to address the fact that Claim 8 was rejected, and amended, because the specification did not enable a person skilled in the art to practice the invention using any "hydrophilic cellulose derivative" other than the hydrophilic polymers specifically recited in the amended claim. Because the applicants agreed with the examiner that the specification did not enable one skilled

in the art to use other "hydrophilic cellulose derivatives" as hydrophilic polymers, Claim 1 cannot have a broader scope than Claim 8. In other words, what was not enabled for Claim 8 cannot be enabled for Claim 1, and the scope of the applicants' express disclaimer of scope extends equally to all claims of the '940 patent. *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319, 1326-27 (Fed. Cir. 2002) (amendment of dependent claims to delete specific compounds disclaims scope of independent claim that could encompass these compounds); *Watts v. XL Sys.*, 232 F.3d 877, 883 (Fed. Cir. 2000) (arguments concerning patentability are relevant to construction of every claim absent a clear indication to the contrary).

5. "Hydrophilic Diluent" and "Hydrophilic Excipient."

Sanofi incorrectly argues that hydrophilic excipients and diluents (claimed in dependent claims) need not differ from the hydrophilic polymer recited in Claim 1, because the specification describes certain chemical species as both hydrophilic polymers and hydrophilic excipients. (Pl.'s Br. at 19.) Under Sanofi's proposed construction, a composition consisting only of an active ingredient and a hydrophilic polymer could infringe all of the claims, because the hydrophilic polymer could also be an "auxiliary substance," as well as a "hydrophilic excipient" and a "hydrophilic diluent." Such a construction renders the dependent claims meaningless. For this reason, Defendants' construction requires that the "hydrophilic polymer" recited in Claim 1 be a different substance than the "auxiliary substance" in the second layer, and a different substance than the "hydrophilic diluent" and the "hydrophilic excipient."

Plaintiffs ignore the express recitations of Claim 1 that distinguish these separate components in the layer structure.

First, the hydrophilic polymer of claim 1 is present in an amount of from 5-90% by weight of the first layer, whereas the hydrophilic excipient is present in an amount of 1-50% of the weight of the layer ('940 patent, JA000095 at col. 3:29-30; Claim 4.) By definition, these

two hydrophilic components must be different since the hydrophilic polymer cannot constitute less than 5.0% of the first layer and the hydrophilic excipient, if present, cannot constitute more than 50% of any layer. *See Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000) (claim limitation reciting a "majority" cannot be construed to encompass a "minority" either literally or under the doctrine of equivalents).

Second, Plaintiffs' argument and the supporting McGinity Declaration incorrectly define hydrophilic cellulose derivatives and microcrystalline cellulose ("MCC") as both hydrophilic polymers and hydrophilic diluents. (Pl.'s Br. at 22-23; McGinity Decl. ¶74.) MCC is not defined as a hydrophilic polymer in the patent, but rather is expressly defined solely as a hydrophilic diluent. '940 patent, JA95 at col. 3: 47-48. By arguing that MCC is a hydrophilic cellulose derivative, Plaintiffs urge that it is a hydrophilic polymer as well, and thus is both a hydrophilic polymer and a hydrophilic diluent. (Pl.'s Br. at 22-23; McGinity Decl. ¶74.) Plaintiffs' argument must fail.

If MCC is a hydrophilic cellulose derivative as Plaintiffs maintain, applicants unequivocally disclaimed a definition of hydrophilic polymer that included hydrophilic cellulose derivatives during prosecution, and MCC is not and cannot be a hydrophilic polymer as posited by plaintiffs.

In addition to the separate definitions provided for each term in the specification, the claims clearly differentiate between the terms hydrophilic polymer and hydrophilic diluent. Under 35 U.S.C. § 112 and well recognized principles of claim differentiation, the hydrophilic diluent of Claim 13 must be other than the hydrophilic polymer of Claim 1. *See, e.g.*, Def.'s. Br. at 18-20.

III. CONCLUSION

For the foregoing reasons, the Defendants respectfully request that the Court adopt the constructions set forth herein.

POTTER ANDERSON & CORROON LLP

By: */s/ David E. Moore*
Richard L. Horwitz (#2246)
David E. Moore (#3983)
D. Fon Muttamara-Walker (#4646)
Hercules Plaza 6th Floor
1313 N. Market Street
P.O. Box 951
Wilmington, DE 19899
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com
fmuttamara-walker@potteranderson.com

Attorneys for Defendants Apotex Inc. , Apotex Corp. and Mylan Pharmaceuticals Inc

Also Filed on Behalf of Defendants Torrent Pharma Inc., Torrent Pharmaceuticals Ltd., Actavis South Atlantic LLC, Par Pharmaceutical, Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited, Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Ltd., Wockhardt Limited, and Wockhardt USA, Inc.

OF COUNSEL:

Steven E. Feldman
Sherry L. Rollo
HUSCH BLACKWELL SANDERS LLP
120 S. Riverside Plaza, 22nd Floor
Chicago, IL 60606
Tel: (312) 655-1500

Dated: April 24, 2009
913401 / 32533 / 32339 (Alfi)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on April 24, 2009, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on April 24, 2009, the attached document was Electronically Mailed to the following person(s):

Jack B. Blumenfeld
Maryellen Noreika
James W. Parrett, Jr.
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
jblumenfeld@mnat.com
mnoreika@mnat.com
jparrett@mnat.com
Counsel for Sanofi-Aventis and Sanofi-Aventis US LLC

John M. Desmarais
Gerald J. Flattmann, Jr.
Alexis Gorton
William T. Vuk
Kirkland & Ellis, L.L.P.
Citigroup Center
153 E. 53rd Street
New York, NY 10022
jdesmarais@kirkland.com
gflattmann@kirkland.com
agorton@kirkland.com
wvuk@kirkland.com
Counsel for Sanofi-Aventis and Sanofi-Aventis US LLC

Alfred John Saikali
Shook Hardy & Bacon
201 S. Biscayne Boulevard
Suite 2400
Miami, FL 33131-4332
asaikali@shb.com
Counsel for Sanofi-Aventis and Sanofi-Aventis US LLC

David J. Margules
Bouchard Margules & Friedlander, P.A.
222 Delaware Avenue, Suite 1400
Wilmington, DE 19801
dmargules@bmf-law.com
Counsel for Actavis South Atlantic LLC and Par Pharmaceutical Inc.

Sanjay B. Sitlani
Axinn, Veltrop & Harkrider LLP
1330 Connecticut Avenue, NW
Washington, DC 20036
jwo@avhlaw.com
jbs@avhlaw.com
Counsel for Actavis South Atlantic LLC and Par Pharmaceutical Inc.

Chad A. Landmon
Axinn, Veltrop & Harkrider LLP
90 State House Square
Hartford, CT 06102-3702
cal@avhlaw.com
Counsel for Actavis South Atlantic LLC and Par Pharmaceutical Inc.

James P. Doyle
Axinn, Veltrop & Harkrider LLP
114 West 47th Street
New York, NY 10036
jpd@avhlaw.com
Counsel for Actavis South Atlantic LLC and Par Pharmaceutical Inc.

Mary Matterer
Morris James LLP
500 Delaware Avenue, Suite 1500
P.O. Box 2306
Wilmington, DE 19899-2306
mmatterer@morrisjames.com
Counsel for Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc.

Christine J. Siwik
Paul J. Molino
Deanne M. Mazzochi
Rakoczy Molino Mazzochi Siwik LLP
Six West Hubbard Street, Suite 500
Chicago, IL 60654
csiwik@rmmslegal.com
paul@rmmslegal.com
dmazzochi@rmmslegal.com
Counsel for Aurobindo Pharma, Ltd. & Aurobindo Pharma USA, Inc.

Steven E. Feldman
Sherry L. Rollo
Husch Blackwell Sanders LLP
120 S. Riverside Plaza, 22nd Floor
Chicago, IL 60606
steven.feldman@huschblackwell.com
sherry.rollo@huschblackwell.com
Counsel for Apotex Inc. and Apotex Corp.

John C. Phillips, Jr.
Brian E. Farnan
Phillips, Goldman & Spence, P.A.
1200 North Broom Street
Wilmington, DE 19806
jcp@pgslaw.com
bef@pgslaw.com
Counsel for Barr Laboratories, Inc.

Ivan M. Poullaos
Winston & S trawn LLP
35 West Wacker Drive
Chicago, IL 60601-9703
ipoullaos@winston.com
Counsel for Barr Laboratories, Inc.

Timothy H. Kratz
Robert J. Waddell Jr.
Robert L. Florence
George J. Barry, III
McGuireWoods LLP
1170 Peachtree Street, Suite 2100
Atlanta, GA 30309
tkratz@mcguirewoods.com
rwaddell@mcguirewoods.com
rflorence@mcguirewoods.com
gbarry@mcguirewoods.com
Counsel for Mylan Pharmaceuticals Inc.

Lynn E. Eccleston
McGuireWoods LLP
1750 Tysons Boulevard, Suite 1800
McLean, VA 22102-4215
leccleston@mcguirewoods.com
Counsel for Mylan Pharmaceuticals Inc.

Frederick L. Cottrell, III
Laura Hatcher
Richards, Layton & Finger
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
cottrell@rlf.com
hatcher@rlf.com
Counsel for Ranbaxy Inc., Ranbaxy Laboratories Limited

Darrell L. Olson
William R. Zimmerman
Knobbe, Martens, Olson & Bear
2040 Main Street, 14th Street
Irvine, CA 92614
dolson@kmob.com
bzimmerman@kmob.com
Counsel for Ranbaxy Inc., Ranbaxy Laboratories Limited

Philip A. Rovner
Potter Anderson & Corroon LLP
1313 N. Market Street, 6th Floor
Wilmington, DE 19801
provner@potteranderson.com
Counsel for Sun Pharmaceutical Industries Inc. and Sun Pharmaceutical Industries Ltd.

Eric C. Cohen
Manotti L. Jenkins
Katten Muchin Rosenman LLP
525 West Monroe Street
Chicago, IL 60661-3693
Eric.cohen@kattenlaw.com
manotti.jenkins@kattenlaw.com
Counsel for Sun Pharmaceutical Industries Inc. and Sun Pharmaceutical Industries Ltd.

Francis J. Murphy, Jr.
Murphy, Spadaro & Landon
1011 Centre Road, Suite 210
Wilmington, DE 19805
fmurphy@msllaw.com
Counsel for Torrent Pharma Inc. and Torrent Pharmaceuticals Limited

Keith D. Parr
Kevin M. Nelson
David B. Abramowitz
Scott B. Feder
Locke Lord Bissell & Liddell LLP
111 South Wacker Drive
Chicago, IL 60606
kparr@lockelord.com
knelson@lordbissell.com
dabramowitz@lordbissell.com
sfeder@lockelord.com
Counsel for Torrent Pharma Inc. and Torrent Pharmaceuticals Limited

Josy W. Ingersoll
John W. Shaw
Karen L. Pascale
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19899
jingersoll@ycst.com
jshaw@ycst.com
kpascale@ycst.com
Counsel for Teva Pharmaceuticals USA Inc.

John L. North
Jeffrey J. Toney
Darcy L. Jones
Sutherland Asbill & Brennan LLP
999 Peachtree Street
Atlanta, Georgia 30309-3996
John.north@sutherland.com
Jeffrey.toney@sutherland.com
Darcy.jones@sutherland.com
Counsel for Teva Pharmaceuticals USA Inc.

Jeffrey L. Moyer
Kelly E. Farnan
Richards, Layton & Finger
One Rodney Square
920 N. King Street
Wilmington, DE 19899
Moyer@rlf.com
Farnan@rlf.com
Attorneys for Defendants Wockhardt USA Inc. and Wockhardt Limited

Mark Boland
Michael R. Dzwonczyk
Chandran B. Iyer
Renita S. Rathinam
Sughrue Mion, PLLC
2100 Pennsylvania Avenue, N.W.
Washington, DC 20037
mboland@sughrue.com
mdzwonczyk@sughrue.com
cbiyer@sughrue.com
rrathinam@sughrue.com
Attorneys for Defendants Wockhardt USA Inc. and Wockhardt Limited

I further certify that on April 24, 2009, the attached document was sent via First Class Mail to the following person(s):

Jeffrey N. Luthi
Clerk, MDL Judicial Panel
One Columbus Circle, N.E.
Room G-255, Feder Judiciary Bldg.
Washington, DC 20002-8004

By: */s/ David E. Moore*
Richard L. Horwitz (#2246)
David E. Moore (#3983)
D. Fon Muttamara-Walker (#4646)
POTTER ANDERSON & CORROON LLP
rhorwitz@potteranderson.com
dmoore@potteranderson.com
fmuttamara-walker@potteranderson.com

877938 / 32533 / 32339 (Alfi)